19 FEDERAL REPUBLIC OF GERMANY

GERMAN PATENT OFFICE

12 OLS
DE 195 01 444 A1

21 File number: 196 01 444.8
22 Application date: 1/19/95
43 Disclosure date: 7/25/96

51 Int. Cl^{6}:
A 61 F 2/16

71 Applicant:

Morcher GmbH, 70374 Stuttgart, DE

74 Representative:

Rotermund + Pfusch Attorney Partnership
70372 Stuttgart

72 Inventor:

Mitschischek, E. Dr.med., 31228 Peine, DE

56 Documents to be taken into consideration for evaluating patentability:

DE	39 01 435 A1
US	53 91 202
US	52 01 763
US	47 10 197
US	40 74 368

54 Intraocular posterior chamber lens and/or two-lens system with such a posterior chamber lens

57 In order to permit patients with retinitis pigmentosa to have a clearly expanded visual field and to permit a clearly improved visual orientation, an intraocular posterior chamber lens with very high positive refractive power (e.g. +60 diopters) combined with an intraocular anterior chamber lens designed as a divergent lens (e.g. with -30 diopters), or preferably with an appropriately designed permanent contact lens. If necessary, using eyeglasses in combination with the posterior chamber lens is possible.

Description

The invention relates to an intraocular posterior chamber lens of a two-lens system and/or a two-lens system with such a posterior chamber lens.

Intraocular lenses are used worldwide as the standard in cataract surgery, i.e. with gray cataracts. In this process, the patient's cloudy lens is removed while retaining the capsular sack (lens capsule) that holds the natural lens and replaced with an artificial intraocular lens, which currently is more and more often mounted within the posterior chamber of the eye, i.e. behind the iris, in the capsular sack. To hold the intraocular lens, haptic elements mounted on it are used that can support themselves in the sulcus ciliaris, i.e. between the iris and the capsular sack, or in the capsular sack, the actually "physiological location."

In the case of degeneration of the macula, i.e. the central area of the retina that normally has the greatest density of photoreceptor cells, using a two-lens system is known from EP 00 92 552 B1, in which the natural lens is replaced with an intraocular posterior chamber lens designed as a divergent lens with very great negative refractive poser and is combined with eyeglasses that have lenses designed as convergent lens with positive refractive power. The intraocular posterior chamber lens, together with the eyeglass lens and the cornea of the eye, forms a telescope system so that an image of the environment that is enlarged in comparison to the conditions in the natural eye is created on the retina of the eye, i.e. the image created on the retina is larger than the degenerated macula in this patient, so that in spite of the damage to the retina, the overall visual capacity is definitely improved.

The document by G. Gerten and H.-H. Koch, "Gray Cataracts in Retinitis Pigmentosa," 1990, published by the Deutschen Retinitis Pigmentosa-Vereinigung e.V. [German Retinitis Pigmentosa Association] in Quickborn, deals with information on patients suffering from retinitis pigmentosa, among other things, in which the areas of the retina surrounding the macula are degenerated or are increasingly degenerating. This type of patient typically suffers from so-called "tubular vision," i.e. more or less sharp vision is possible only in a narrow central visual field, presuming that there is no cataract. In Section 4.1 "Intervention Prognosis" on page 29 of the document mentioned above, there is an explanation that, in connection with retinitis pigmentosa, if there is simultaneously a cataract, the natural lens of the eye can be replaced by an artificial intraocular lens, whereby the "improvement of the visual impression naturally consisting of an expansion of the visual field" is not possible.

The task of the invention is now to make possible a significantly improved visual spatial orientation for patients with retinitis pigmentosa.

According to the invention, this task is solved with a two-lens system of the type mentioned at the beginning, in which the intraocular posterior chamber lens is designed as a convergent lens with very high positive refractive index, combined with a divergent lens with greater negative refractive index that is mounted near the cornea of the eye and/or can be worn.

The invention is based, on one hand, on the general concept of simulating the optical system formed by the cornea of the eye and the artificial two-lens system of the invention with a more or less strong angle characteristic in comparison to the optical system of a normal natural eye, and on the other, on the surprising knowledge that the image of the environment that is created on the retina and is necessary reduced in comparison to the conditions in an eye with normal vision, can be very clearly recognized. In this way, for the first time it is possible for the

patient suffering from retinitis pigmentosa to have a definite expansion of the visual field with good recognition capability of the objects appearing in the visual field.

Preferably, the posterior chamber lens has haptics for fixation in the capsular sack, whereby these haptics are designed in an especially preferred manner so that, on one hand, they extend the capsular sack in a circular manner and on the other, push the intraocular lens in a pronounced manner toward the back, in the direction of the retina, against the rear part of the capsular sack.

On one hand, this achieves a fixation of the posterior chamber lens so that the position is especially secure since the lens is supported by the haptics practically on the entire equator of the capsular sack and in this way on the entire ciliary musculature, and by way of the reverse side of the lens at the central area of the capsular sack, which is thereby extended. In this way, it can definitely be ensured that the intraocular posterior chamber lens will not make be able to have any tipping movements after surgery, which have an especially negative effect on the optical properties of a multi-lens system. On the other hand, this embodiment makes it possible for the posterior chamber mounted in the beam path to lie especially close to the retina, so that on one hand irritations of the iris, e.g. irido-capsular adhesions, can be safely prevented and on the other, the retina-side refractive boundary layer of the entire optical system made up of the cornea and the artificial two-lens system can lie closer to the retina, which is desirable with respect to an enlarged visual field.

The divergent lens of the two-lens system can be designed as an intraocular anterior chamber lens or - especially in younger patients - as a contact lens, preferably as a permanent contact lens, as they are called, which can remain on the eye for a longer period of time.

In addition, with respect to preferred characteristics of the invention, reference is made to the claims and the following description of preferred embodiments that will be explained using the drawings.

They show:

Fig. 1 shows a schematic cross section illustration of an eye with normal vision,

Fig. 2 shows a cross section illustration of the eye with the two-lens according to the invention,

Fig. 3 shows a front view of the intraocular posterior chamber lens and

Fig. 4 shows a side view of the posterior chamber lens corresponding to arrow IV in Fig. 3.

According to fig. 1, the light enters through the cornea 1 into the eye 2, passes through the anterior eye chamber 4 lying between cornea 1 and iris 3 and passes through the pupil 5 bordered by the iris 3. Then the light passes through the posterior chamber 7 of eye 2 formed between iris 3 and lens 6, and following that the lens 6 and the vitreous body 8, which fills the space between lens 6 and retina 9. On the retina 9, the light is intercepted by the photoreceptor cells (rods and cones) and transformed into nerve impulses, which are sent over the optic nerve 10 to the visual center of the brain.

Cornea 1 and chambers 4 and 7 and the lens 6 essentially form the optical system, i.e. the natural lens system of eye 2, which displays an object 11 that is present in the visual field of the eye 2 and is shown schematically as an arrow in fig. 1, in a way that is basically known, as a reduced image 12 on retina 9. In this process, part 11' of object 11, which lies close to, or at, the optical axis 13 of eye 2, appears as image section 12' on macula 9', i.e. the central area of retina 9 adjacent to the optical axis, which has a very high concentration of photoreceptor cells and accordingly makes a very high resolution possible, i.e. details and contours of image part 11' are

especially recognizable. With increasing distance from the macula 9', the photoreceptor cell density of retina 9 is lower, and thus the image resolution capability is lower. This is barely noticed by people with normally-functioning eyes, since the eyes continuously make involuntary small sweeping movements, so that "interesting" or fast-moving objects, which at first appear only on the areas of retina 9 that are at a greater distance from macula 9', are quickly "scanned" by the eye. This results in a uniformly sharp visual impression within a very wide visual filed.

In patients with retinitis pigmentosa, the retina 9 is greatly degenerated and non-functioning outside a narrow area close to the optical axis 13 of eye 2, i.e. especially outside the macula 9'. In the example in fig. 1, part 11' of the object and the associated image 12' can still be recognized. Objects or object areas at a greater distance from the optical axis 13 are not perceived at all. The result is that the patients suffer from pronounced "tubular vision" and especially the vision used for orientation is very restricted. Lacking a perceivable visual impression of objects and/or object parts whose images appear on non-functioning areas of the retina, the eye 2 also does not make any automatic sweeping movements in the direction of such objects. Because of this, the environment can essentially no longer be perceived by the patient in a practical way.

Now, in this case, a very significant improvement can be achieved with the invention.

The natural lens 6 that is still often cloudy and unusable in patients with retinitis pigmentosa due to a cataract is removed, while leaving in place the capsular sack 14 that surrounds lens 6 and is opened surgically on the front side, and replaced with an intraocular posterior chamber lens 15 that according to the invention has a very high refractive power that is about three times as high as the refractive power of a healthy natural lens 6 and lies at approx. +60 diopters. As will be explained further below, this lens is arranged as far to the rear as possible in the eye 2, i.e. at the greatest possible difference from the cornea 1 and to do this, is preferably fastened in the capsular sack 14 in a way that is described further below.

For compensation of the excessively positive refractive power of the posterior chamber lens, a divergent lens in the form of a contact lens 17 that can be arranged on the outside of the cornea 1. The negative refractive power of this lens 16 and/or contact lens 17 has a magnitude of -30 diopters.

Basically, it is also possible to use eyeglasses instead of the anterior chamber lens 16 and/or the contact lenses 17. Because of the greater distance of the eyeglass lenses from the eye, a negative refractive force on the order of -20 diopters is adequate.

The two-lens system 15/16 and/or 15/17 works similarly to a "reverse telescope," i.e. the object 11 is imaged on the part of retain 9 that is still functional, even in the case of retinitis, especially the macula 9', as a clearly small image 12" in comparison to the eye 2 with normal vision. What this means is that the visual field of the eye 2 shown in fig. 2 is definitely expanded in spite of large areas of the retina 9 that are virtually non-functional.

Surprisingly it has been found that the advantages of the visual speed expansion far outweighs the reduction of the images on the retina. This can certainly be explained, not only by the fact that the photoreceptor cell density is comparatively high in the area of the macula 9 and/or the adjacent areas of retina 9, even in patients with retinitis pigmentosa. It is much more a case here that the "image evaluation" of the brain also plays a role, which "knows" or in a short time "learns," what size the objects associated with the respective images on the retina 9 have, so that the patient perceives these objects in the "proper size."

According to figs. 3 and 4, the posterior chamber lens 15 is preferably designed as a convergent lens only in a central area 15'. This insures that the maximum thickness of the

posterior chamber lens 15 remains small in the direction of the optical axis 13, in spite of the high refractive power. This offers the advantages that a large distance is ensured between iris 3 and posterior chamber lens 15 and in this way, any irritations of the iris 3 can be prevented. The diameter of area 15', which is e.g. 5.5 mm, is slightly larger than the normal diameter of the pupil 5, so that practically all of the light passing through the pupil 5 can pass through the convergent lens area 15'.

A ring-shaped area 15' connects radially outward on the convergent lens area 15', the outer edge of which is well rounded, especially on the side turned toward the retina 9. Typically, the outer edge has a profile that is approximately semi-circular.

On two diametrically opposite circumference sections of the ring-shaped area 15', two laminar-shaped extensions 18 are formed, which in comparison to the plane of the ring-shaped area 15' are tipped about 15° in the direction of the front side of lens 15. In this process, the extensions 18 transition into the ring-shaped area 15" without sharp edges and preferable curved.

The extensions 18 can be connected to the ring-shaped area 15" with a certain elasticity in such a way that the lens 15 increases its distance from a plane containing the outer edges of extensions 18 if forces in radial inward direction perpendicular to the optical axis 13 act on the outer edges of both extensions 18.

The outer edges of extensions 18 are rounded like the outer edge of the ring-shaped area 15" and in turn have e.g. a semi-circular edge profile.

The circumference edge of each of the extensions 18 gradually changes into an open, circular loop 19, which extends from one extension 18 to the area of the other extension and forms an elastic resilient bow that has a slightly spiral form in relaxed state in the axial view of lens 15, such that the free end of each loop 19 is somewhat further from the center of the lens that the connecting areas of the loops 19 to the extensions 18.

As can especially be seen in fig. 4, each loop 19, in relaxed state, has a certain coil-like pitch so that the lens 15 can be "screwed into" the opened capsular sack 14 during surgical implantation. In order to make the installation of the lens 15 into the capsular sack 14 easier, an opening 20 can be provided in at least one of the extensions 18 for insertion of a surgical instrument.

In addition, the loops 19 have a circular or oval cross section and free ends with ball-shaped rounding.

After installing the lens 15 in the capsular sack 14, the loops 19 form a practically closed ring and the extensions 18 form two stable, elastic spokes that hold this ring, whereby both the loops 19 and also the extensions 18 forming the spokes attempt to stretch the equator of the capsular sack 14 in a ring shape, and accordingly the ciliary musculature 21 that holds the capsular sack on the outside at the equator. Because of the ring-shaped support at the equator of the capsular sack 14, any fissures that may be present in the ciliary musculature 21 are bridged so that even with contractions of the ciliary musculature 21, which in the healthy eye serve to deform the lens 6 (see fig. 1) and thus result in the adaptation involved, no tipping of lens 15 can occur.

In addition, the position of lens 15 in the capsular sack 14 is also secured in that lens 15 attempts to stretch the capsular sack 14 back toward retina 9 because of the angled extensions 18, whereby the capsular sack 14 contacts both the outer edge of the ring-shaped area 15" and the center reverse side of area 15' with a certain amount of tension.

To the extent that the ciliary musculature 21 causes a change in the flexing angle between the extensions 18 and the ring-shaped area 15" of the lens during contractions, a displacement of

the lens 15, although slight, occurs in the direction of optical axis 13 of eye 2, whereby the axial distance between the posterior chamber lens 15 and the anterior chamber lens 16 and/or the contact lens 17 changes somewhat, with the result that the ciliary musculature 21 can cause a limited adaptation of eye 2.

The relatively small maximum thickness of lens 15 in the direction of optical axis 13 insures that the average distance of the front and reverse side of the lens 15 from the anterior chamber lens 16 and/or the contact lens 17 is comparatively large, while this distance is made still greater by the arrangement of lens 15 that is stressed toward the back in capsular sack 14. Because of this, in comparison to a basically conceivable lens 15 with enlarged convergent lens area 15' both with respect to the diameter and with respect to thickness, a pronounced wide angle effect of the two-lens system 15/16 and/or 16/17 according to the invention can be achieved.

The anterior chamber lens 16 and/or the contact lens 17, which are both designed as highly divergent lenses are each known - as single lens systems - for correction of extreme myopia (nearsightedness), so design details do not have to be explained.

Patent Claims

1. Two-lens system with intraocular posterior chamber lens, characterized in that the intraocular posterior chamber lens (15) is designed as a convergent lens with very high positive refractive power and is combined with a divergent lens (16, 17) with very negative refractive power that is arranged near the cornea and/or can be worn.
2. Two-lens system according to claim 1, characterized in that the refractive power of the posterior chamber lens (15) is approx. 3 times as high as the refractive power of a natural eye lens (6) and lies at approx. +60 diopters in the aqueous humor.
3. Two-lens system according to claim 1 or 2, characterized in that the divergent lens (16, 17) has a negative refractive power, with a magnitude on the order of approx. -30 diopters in the aqueous humor.
4. Two-lens system according to one of claims 1 to 3, characterized in that the posterior chamber lens (15) is designed to be fastened in the capsular sack (14).
5. Two-lens system according to one of claims 1 to 4, characterized in that the posterior chamber lens (15) has haptics (18, 19), by which the lens (15) is stressed backwards in the eye (2) toward the retina (9), against the capsular sack (14).
6. Two-lens system according to one of claims 1 to 5, characterized in that the divergent lens is designed as a permanent contact lens (17) that can be worn on the eye (2) over the long term.
7. Posterior chamber lens, especially for a two-lens system according to one of claims 1 to 6, characterized in that on a central convergent lens area (15), a ring-shaped area (15") connects radially outward, which on its outside edge is provided with haptic elements (18, 19), which are angled in a pronounced way - e.g. by about 15° - toward the front side of the lens.

---

3 Page(s) of drawings follow

- Blank page -

[see original for 3 pages of figures]